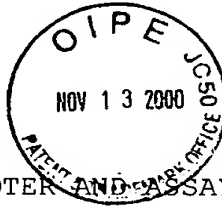


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alan R. Tall
Serial No.: 09/560,372
Filed : April 28, 2000
For : HUMAN ABC1 PROMOTER AND ASSAY BASED THEREON



1185 Avenue of the Americas
New York, New York 10036
November 8, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, Applicant would like to direct the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (**Exhibit A**). Copies of the disclosures listed below as items 1-35 are attached as **Exhibits 1-35**, respectively.

1. Brousseau, M.E. et al., "Novel Mutations in the Gene Encoding ATP Binding Cassette 1 In Four Tangier Disease Kindreds", *J.Lipid Res.*, 41(3): 433-441, March 2000; (**Exhibit 1**)
2. Brown, M.S. et al., "The SREBP Pathway: Regulation of Cholesterol Metabolism by Proteolysis of a Membrane-bound Transcription Factor", *Cell*, 89(3): 331-340, May 1997; (**Exhibit 2**)
3. Bodzioch, M. et al., "The Gene Encoding ATP-Binding Cassette Transporter 1 is Mutated in Tangier Disease" *Nat. Gen.*, 22(4): 347-351, August 1999; (**Exhibit 3**)

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4. Bruce, C. et al., "Plasma Lipid Transfer Proteins High density Lipoproteins, and Reverse Cholesterol Transport", *Annual Rev. Nutr.*, 18: 297-330, 1998; (**Exhibit 4**)
5. Castelli, W.P. et al., "Incidence of Coronary Heart Disease and Lipoprotein Cholesterol Levels", *JAMA*, 256(20): 2835-2838, November 1986; (**Exhibit 5**)
6. Christenson, L.K. et al., "Oxysterol Regulation of Steroidogenic Acute Regulatory Protein Gene Expression", *J. Biol. Chem.*, 273(46): 30729-30735, November 1998; (**Exhibit 6**)
7. Croop, J.M., "Evolutionary Relationships among ABC Transporters", *Methods Enzymol*, 292: 101-116, 1998; (**Exhibit 7**)
8. Feltkamp, D. et al., "Identification of a Novel DNA binding site for Nuclear Orphan Receptor OR1", *J. Biol. Chem.*, 274(15): 10421-10429, April 1999; (**Exhibit 8**)
9. Hamon, Y. et al., "Interleukin-1beta Secretion is Impaired by Inhibitors of the ATP Binding Cassette Transporter, ABC1", *Blood*, 90(8): 2911-2915, October 1997; (**Exhibit 9**)
10. Hulten, L.M. et al., "Oxysterols present in Atherosclerotic Tissue Decrease the Lipoprotein Lipase Messenger RNA in Human Monocyte-Derived Macrophages", *J. Clin. Invest.*, 97(2): 461-468, January 1996; (**Exhibit 10**)
11. Janowski, B.A. et al., "An Oxysterol Signaling Pathway Mediated by the Nuclear Receptor LXR Alpha" *Nature*, 383:

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728-731, October 1996; (**Exhibit 11**)

12. Klucken, J. et al., "ABCG1 (ABC8), The Human Homolog of the Drosophila White Gene is a Regulator of Macrophage Cholesterol and Phospholipid Transport", *Proc. Natl. Acad. Sci.*, 97(2): 817-822, January 2000; (**Exhibit 12**)
13. Kronqvist, R. et al., "The Effect of Interleukin 1 Beta on the Biosynthesis of Cholesterol, Phosphatidylcholine, and Sphingomyelin in Fibroblasts, and on Their Efflux from Cells to Lipid-Free Apolipoprotein A-I", *Eur. J. Biochem.*, 262(3): 939-946; (**Exhibit 13**)
14. Lala, D.S. et al., "Activation of the Orphan Nuclear Receptor Steroidogenic Factor 1 by Oxysterols", *Proc. Natl. Acad. Sci.*, 94(10): 4895-4900, May 1997; (**Exhibit 14**)
15. Langmann, T. et al., "Molecular Cloning of the Human ATP-Binding Cassette Transporter 1 (hABC1): Evidence for Sterol-Dependent Regulation in Macrophages", *Biochem. Biophys. Res. Commun.*, 257(1): 29-33, April 1999; (**Exhibit 15**)
16. Lawn, R.M. et al., "The Tangier Disease Gene Product ABC1 Controls the Cellular Apolipoprotein-Mediated Lipid Removal Pathway", *J. Clin. Invest.*, 104(8): 25-31, October 1999; (**Exhibit 16**)
17. Lehmann, J.M. et al., "Activation of the Nuclear Receptor LXR by Oxysterols Defines A New Hormone Response Pathway", *J. Biol. Chem.*, 272(6): 3137-3140, February. 1997; (**Exhibit 17**)

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18. Luciani, M.F. et al., "Cloning of Two Novel ABC Transporters Mapping on Human Chromosome 9", *Genomics*, 21:(1) 150-159, May 1994; (**Exhibit 18**)
19. Luo, Y. et al., "Sterol Upregulation of Human CETP Expression In Vitro and in Transgenic Mice by an LXR Element", *J. Clin. Invest.*, 105: 513-520, February 2000; (**Exhibit 19**)
20. Marcil, M. et al., "Cellular Cholesterol Transport and Efflux in Fibroblasts are Abnormal in Subjects with Familial HDL Deficiency", *Arterioscler. Thromb. Vase. Biol.*, 19 (1): 159-169, January 1999; (**Exhibit 20**)
21. Marcil, M. et al., "Mutations in the ABC1 Gene in Familial HDL Deficiency with Defective Cholesterol Efflux", *Lancet*, 354(9187): 1341-1346, October 1999; (**Exhibit 21**)
22. Ohlsson, B.J. et al., "Oxidized Low Density Lipoprotein Inhibits Lipopolysaccharide-Induced Binding of Nuclear Factor-KappaB to DNA and the Subsequent Expression of Tumor Necrosis Factor-alpha and Interleukin-1beta in Macrophages", *J. Clin. Invest.*, 98(1): 78-89, July 1996; (**Exhibit 22**)
23. Orso, E. et al., "Transport of Lipids from Golgi To Plasma Membrane is Defective in Tangier's Disease Patients and ABC1-Deficient Mice", *Natural Genetics*, 24(2): 192-196, February 2000; (**Exhibit 23**)
24. Panousis, C.G. et al., "Regulation of Cholesterol Distribution in Macrophage Derived Foam Cells by Interferon-gamma", *J. Lipid Res.*, 41(1): 75-83, January

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2000; (**Exhibit 24**).

25. Peet, D.J. et al., "Cholesterol and Bile Acid Metabolism Are Impaired in Mice Lacking the Nuclear Oxysterol Receptor LXR Alpha", *Cell*, 93(5): 693-704, May 1998; (**Exhibit 25**)
26. Remaley, A.T. et al., "Decreased Reverse Cholesterol Transport From Tangier Disease Fibroblasts. Acceptor Specificity and Effect of Brefeldin On Lipid Efflux", *Arterioscler Thromb. Vasc. Biol.*, 17(9): 1813-1821, September 1997; (**Exhibit 26**)
27. Remaley, A.T. et al., "Human ATP-Binding Cassette Transporter 1 (ABC1): Genomic Organization and Identification of the Genetic Defect in the Original Tangier Disease Kindred", *Proc. Natl. Acad. Sci.*, 96(22): 12685-13690, October 1996; (**Exhibit 27**)
28. Rothblat, G.H. et al., "Cell Cholesterol Efflux: Integration of Old and New Observations Provides New Insights", *J. Lipid Res.*, 40(5): 781-796, May 1999; (**Exhibit 28**)
29. Rust, S. et al., "Assignment of Tangier Disease to Chromosome 9q31 By a Graphical Linkage Exclusion Strategy", *Natural Genetics*, 20(1): 96-98, September 1998; (**Exhibit 29**)
30. Rye, K.A. et al., "Evidence that Cholesterol Ester Transfer Protein-Mediated Reductions in reconstituted High density Lipoprotein size Involve Particle Fusion", *J. Biol. Chem.*, 272(7): 3953-3960, February 1997; (**Exhibit 30**)

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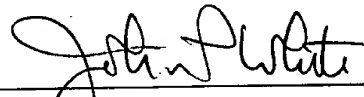
31. Seol, W. et al., "Isolation of Proteins that Interact Specifically With the Retinoid X Receptor: Two Novel Orphan Receptors", *Mol. Endocrinol*, 9(1): 72-85, January 1995; (**Exhibit 31**)
32. Song C. et al., "Ubiquitous Receptor: A Receptor that Modulates Gene Activation By Retinoic Acid and Thyroid Hormone Receptors", *Proc.Natl. Acad Sci.*, 91(23): 10809-10813, November 1994; (**Exhibit 32**)
33. Teboul, M. et al., "OR-1, A Member of the Nuclear Receptor Superfamily That Interacts With the 9-cis-retinoic Acid Receptor", *Proc.Natl. Acad Sci.*, 92(6): 2096-2100, March 1995; (**Exhibit 33**)
34. Shipley, J.M., "Metalloelastase is Required for Macrophage-Mediated Proteolysis and Matrix Invasion in Mice", *Proc.Natl. Acad Sci.*, 93(9): 3942-3946, April 1996; (**Exhibit 34**) and
35. Willy, P.J., "LXR, A Nuclear Receptor that Defines A Distinct Retinoid Response Pathway", *Genes Dev.*, 9(9): 1033-1045, May 1995; (**Exhibit 35**)

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone at the number provided below.

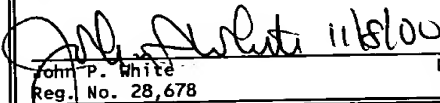
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No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. If any such fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
 John P. White Reg. No. 28,678	Date